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## COST-EFFECTIVENESS OF CLOSTRIDIAL COLLAGENASE OINTMENT ON WOUND CLOSURE IN PATIENTS WITH DIABETIC FOOT ULCER

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**OBJECTIVES:** Determine the cost-effectiveness of clostridial collagenase ointment (CCO) plus surgical sharp debridement (SSD) relative to the standard of care (SC) plus SSD on wound closure for the treatment of diabetic foot ulcer (DFU). SC was defined as offloading plus daily wound care/dressings. **METHODS:** A 3-stage Markov model was used to predict the expected costs and outcomes of wound closure for CCO and SC. The 3 stages were open wound, epithelialization, and death. Outcome data used in the analysis were taken from a randomized clinical trial that directly compared CCO and SC. The primary outcome was the proportion of patients achieving a closed epithelialized wound. Transition probabilities for the Markov states were estimated from the clinical trial. A 52-week time horizon was used to determine the number of closed epithelialized wounds and the expected costs for the two therapies. Resource utilization was based on the treatment regimen used in the clinical trial. Costs were derived from standard cost references and medical supply wholesalers. The economic perspective taken was that of the payer. **RESULTS:** A total of 55 patients were included (28 for CCO and 27 for SC). Expected direct costs per patient for DFU were $2099 for CCO and $2376 for SC (a cost-savings of $278 for CCO). Patients treated with CCO had, on average, 35 ulcer-free weeks compared to 28 weeks for SC. CCO therapy had a higher probability of healing at 52 weeks compared to SC (89% vs. 80%, respectively). The cost per closed wound week was 1.4 times higher for SC compared to CCO ($61/week versus $85/week, respectively). **CONCLUSIONS:** CCO was cost-effective over SC, yielding better outcomes at a lower cost in patients with DFU. Health care providers should consider CCO as a more effective alternative to SC and an effective adjunct therapy to sharp debridement.

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## HEALTH ECONOMIC EVALUATION OF CANAGLIFLOZIN IN THE TREATMENT OF TYPE 2 DIABETES MELLITUS IN BELGIUM

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**OBJECTIVES:** To evaluate the cost-effectiveness of canagliflozin in dual therapy (plus metformin) compared to sitagliptin and glimepiride, and in triple therapy compared to pioglitazone (plus metformin), sitagliptin (plus glimepiride and metformin) and as add on to insulin (plus metformin) respectively in the Belgian setting from the public payers perspective. **METHODS:** The IMS CORE Diabetes Model was used to evaluate, based on head-to-head clinical trials, the cost-effectiveness of canagliflozin (assuming 70/30 dose distribution for the 100mg and 300mg respectively) versus the aforementioned comparators using Belgian-specific data, where available. Costs were obtained from official sources, literature and the IMS Hospital Disease Database and are reported in 2013 Euro (€).An annual discount rate of 3% was applied on costs and 1.5% on effects. **RESULTS:** The cost-effectiveness analyses indicate that in dual therapy when compared with sitagliptin and glimepiride, canagliflozin is expected to be cost–effective with an ICER of 6,992 €/QALY gained (with an incremental cost and QALY of €366 and 0.052) and 3,364 €/QALY gained (with an incremental cost and QALY of €410 and 0.122), respectively. In both triple therapies, treatment with canagliflozin appears to be a dominant strategy resulting in QALY gains and cost-savings. As an add on to insulin (plus metformin), canagliflozin is cost–effective with an ICER of 11,929 €/QALY gained (with an incremental cost and QALY of €721 and 0.060). The deterministic sensitivity analysis revealed that the results are sensitive to time horizon (with a time horizon of 10 years the ICER increases to a level in range €20.000-30.000). Probabilistic sensitivity analysis showed that in all the comparisons, canagliflozin appears to be the dominant strategy with a large proportion (about 48%) of cases being in the south-east quadrant. **CONCLUSIONS:** Canagliflozin 100 mg or 300 mg (70/30 dose split) provides economic value when used in treatment of type 2 diabetes in Belgium.

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## TREATMENT OF TYPE 2 DIABETES IN COLOMBIA: ECONOMIC EVALUATION OF SAXAGLIPTIN/METFORMIN EXTENDED-RELEASE (XR) FIXED-DOSE COMBINATION (FDC)

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**OBJECTIVES:** To evaluate the economic impact of using saxagliptin/metformin XR FDC *versus* sulfonylurea (SU) plus metformin (MET) in Colombia, in people with type 2 diabetes (T2DM) who do not achieve treatment goal only with MET. **METHODS:** A discrete event simulation model (Cardiff diabetes model) based on UKPDS 68 was used to simulate disease progression and to estimate the economic and health treatment consequences in people with T2DM. Epidemiologic and clinical efficacy parameters were obtained from the literature. Cost of medication was obtained from country level drug prices, SISMED and Farmaprecios; cost of macro and microvascular events were based on POS tariffs, SOAT Manual and consultation with a local expert. A 20-year time horizon was assumed. Costs and health outcomes were discounted at 3% annually. Deterministic and probabilistic sensitivity analysis were also performed. **RESULTS:** The group treated with saxagliptin/metformin XR had fewer non-fatal events and episodes of hypoglycemia than the SU plus MET treated group. The model also predicted a lower number of fatal macrovascular events for the saxagliptin/metformin XR group (159 *vs.* 162). In both treatment groups the costs were driven by drug and treatment costs associated with myocardial infarction. The total cost of saxagliptin/metformin XR group over 20 years was lower than SU plus MET treated group (US$ 14,454,257 *vs.* US$ 14,735,176). Treatment with saxagliptin/metformin XR resulted in a greater number of quality-adjusted life years (QALYs) and life-years gained (LYG) than the SU combination (10,203 *vs.* 9,955 and 12,207 *vs.* 12,190 respectively). Cost-effectiveness results were robust according to sensitivity analysis. **CONCLUSIONS:** according to the model cost-effectiveness results in Colombia, saxagliptin/metformin XR FDC would be the dominant treatment option compared to SU as add-on to MET, for people with T2DM after failure of treatment only with MET.

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## COST-EFFECTIVENESS ANALYSIS OF CANAGLIFLOZIN (CANA) VERSUS DAPAGLIFLOZIN (DAPA) AS AN ADD-ON TO METFORMIN (MET) IN PATIENTS WITH TYPE 2 DIABETES MELLITUS (T2DM) IN THE UNITED STATES

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**OBJECTIVES:** CANA and DAPA are sodium glucose co-transporter 2 inhibitors indicated for the treatment of adults with T2DM as monotherapy and as add-on combination therapy with other antihyperglycemic agents. The objective of this analysis was to evaluate the cost-effectiveness of using CANA 300mg versus using DAPA 10mg in dual therapy (with MET background) in patients with inadequate A1C control. **METHODS:** A validated health economics model, Economic and Health Outcomes (ECHO)–T2DM, was used to estimate 30-year outcomes associated with using each treatment in patients as an add-on to MET monotherapy. Treatment effects for A1C, weight and the probability of hypoglycemia were obtained from a Bayesian Network Meta-Analysis (NMA) of 52 (+/-4) week trials of subjects inadequately controlled on MET monotherapy. For parameters unavailable in the NMA (i.e., SBP, LDL, HDL and rates of AEs), values were obtained from a post-hoc analysis of pooled data from two trials of subjects receiving CANA and MET. In the model, treatment was intensified when A1C exceeded 7.5%, first by adding basal insulin and subsequently by adding prandial insulin. Utility decrements and U.S. costs associated with key macrovascular and microvascular heath states and AEs were sourced from the literature. All costs and benefits were discounted at 3%. **RESULTS:** CANA dominated DAPA; CANA was associated with both cost savings ($3,204) and more Quality Adjusted Life Years (0.22). The reductions in the relative risks of microvascular (up to 4.4%) and macrovascular events (up to 1.7%) as well as a delay in the use of insulin are the key drivers. **CONCLUSIONS:** This simulation suggests that CANA will not only produce cost-savings, but also result in QALY gains versus DAPA in the treatment of patients inadequately controlled on MET in the US.

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## DAPAGLIFLOZIN: COST-EFFECTIVENESS AS AN ADD-ON THERAPY TO METFORMIN IN THE TREATMENT OF TYPE 2 DIABETES (T2DM) IN ARGENTINA AND CHILE

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**OBJECTIVES:** To compare the cost-effectiveness of dapagliflozin versus sulfonylurea (SU) added to metformin in people with T2DM inadequately controlled on metformin alone, in Argentina and Chile. **METHODS:** A discrete event simulation model (Cardiff diabetes model) based on UKPDS 68 was used to simulate disease progression and to estimate the economic and health treatment consequences in people with T2DM. Epidemiologic and clinical efficacy parameters were obtained from the literature. The cost of medication was based on country level drug prices; the cost of macro- and microvascular events was based on tariffs from the social security system of Argentina and the National Health Insurance (FONASA) of Chile. Costs were expressed in US dollars ($). A 20-year time horizon and the payer's perspective were assumed. Costs and health outcomes were discounted at 5% and 3% in Argentina and Chile, respectively. Deterministic and probabilistic sensitivity analyses (PAS) were performed. **RESULTS:** Comparison of dapagliflozin add-on to metformin versus SU addition to metformin showed an incremental benefit of 0.376 QALYs (95%CI: 0.368; 0.385) in Argentina and 0.422 QALYs (95%CI: 0.411; 0.432) in Chile. In both countries, the total cost of the dapagliflozin cohort was higher than that of the SU cohort (Incremental cost: Argentina: $3,400; Chile: $2,423). The calculated Incremental Cost-Effectiveness Ratio (ICER) was $9,036 and $5,745 per QALY in Argentina and Chile, respectively. Using WHO's criteria, dapagliflozin compared to the SU treatment strategy has 88% probability for Argentina and 99% for Chile of being highly cost-effective (ICER< 1 GDP per capita). The results were robust to sensitivity analysis. **CONCLUSIONS:** Dapagliflozin in combination with metformin is a cost-effective treatment option for patients who are inadequately controlled with metformin monotherapy in Argentina and Chile.

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## COMPARATIVE COST-EFFECTIVENESS OF BECAPLERMIN GEL ON WOUND HEALING AND AMPUTATION IN PATIENTS WITH DIABETIC FOOT ULCER

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**OBJECTIVES:** Determine the cost-effectiveness of becaplermin gel* on wound healing and amputation for the treatment of diabetic foot ulcers (DFUs). **METHODS:** A 4-stage Markov model was used to predict the expected costs and outcomes

of wound healing and amputation rates for becaplermin and non-becaplermin DFU cohorts over a 1-year time period. Outcome data used in the analysis were derived from a propensity score matched cohort of 24,898 subjects with DFU from the Curative Health Services database from 1998-2004 who were followed for 20 weeks. Primary outcomes of interest were ulcer-free weeks and rates of amputation. Costs for amputation and becaplermin gel* were derived from standard cost references and medical supply wholesalers. Total weekly costs per episode of DFU care were estimated from a large retrospective claims database. Transition probabilities for healing and amputation were derived from the aforementioned propensity score matched cohorts. Ulcer recurrence was estimated from the medical literature. Utilization for becaplermin was calculated using the manufacturer's recommended dosing algorithm. The economic perspective taken was that of the payer. Costs are reported in 2013 US dollars. **RESULTS:** Overall, 2,394 (9.6%) received becaplermin. Of those who received becaplermin, 33.5% healed at 20 weeks compared to 26.5% who did not receive becaplermin ($p<0.0001$). In addition, the percent of patients requiring amputation were significantly ($p<0.0001$) lower in the becaplermin cohort (4.9% versus 6.4%, respectively). Patients treated with becaplermin had substantially higher ulcer-free weeks compared to non-becaplermin patients (16.1 versus 12.5 weeks, respectively). Expected annual direct costs for DFU were $20,885 for becaplermin and $23,506 for non-becaplermin. **CONCLUSIONS:** Becaplermin was economically dominant over standard therapy, providing better outcomes at a lower cost in patients with DFU. In addition, becaplermin is more effective in wound healing and preventing amputation, thereby decreasing long-term costs for DFU. *Regranex®, Smith & Nephew Biotherapeutics, Fort Worth, Texas

**PDB65**

**COST-EFFECTIVENESS OF SMALL INTESTINAL SUBMUCOSA EXTRACELLULAR MATRIX ON WOUND CLOSURE IN PATIENTS WITH DIABETIC FOOT ULCER**

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**OBJECTIVES:** Determine the cost-effectiveness of small intestinal submucosa extracellular matrix (SISEM)* relative to human fibroblast-derived dermal substitute (HF-DDS)† on wound closure for the treatment of diabetic foot ulcers (DFUs). **METHODS:** A 2-stage Markov model was used to predict the expected costs and outcomes of wound closure for SISEM and HF-DDS. Outcome data used in the analysis were taken from a 12-week randomized clinical trial that directly compared SISEM and HF-DDS. Twenty-six patients completed the study; 13 for SISEM and 13 for HF-DDS. The primary outcome of interest was ulcer-free days. Transition probabilities for the Markov states were estimated from the clinical trial. Resource utilization was based on the treatment regimen used in the clinical trial. Costs were derived from standard cost references and medical supply wholesalers. The economic perspective taken was that of the payer. No cost discounting was performed due to the short duration of the study. **RESULTS:** Ten wounds closed in the SISEM group (77%), with an average time to closure of 36 days, while 11 wounds closed in the HF-DDS group (85%), with an average closure time of 41 days. No significant difference was found in the time to closure or in the percentage of wound closure between the two groups ($p=0.73$). Expected direct costs per patient for DFU were $2,949 for SISEM and $5,282 for HF-DDS. Patients treated with HF-DDS incurred total treatment costs that were approximately 1.8 times higher than those treated with SISEM. The estimated cost per ulcer-free day was more than 1.5 times higher HF-DDS vs. SISEM. **CONCLUSIONS:** SISEM yielded similar outcomes at a lower cost in patients with DFU. Health care providers should consider SISEM as a cost-saving alternative to HF-DDS. *OASIS®, Smith & Nephew Biotherapeutics, Fort Worth, Texas †Dermagraft®, Shire Regenerative Medicine Inc., San Diego, California

**PDB66**

**ADDING VILDAGLIPTIN TO STANDARD CARE IN PATIENTS WITH TYPE 2 DIABETES IN COLOMBIA- A COST-EFFECTIVENESS ANALYSIS**

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**OBJECTIVES:** Vildagliptin is a DPP-4 inhibitor available in Colombia for the treatment of diabetes mellitus as monotherapy or in combination with metformin, sulfonylureas, or insulin. Our aim was to determine the cost-effectiveness of the addition of vildagliptin to metformin, or sulfonylureas for the management of type 2 diabetes in Colombia. **METHODS:** We developed a hybrid decision Markov model to simulate the level of glycemic control and the health states associated with macrovascular complications (myocardial infarction, disabling stroke, and heart failure), nephropathy and death in a hypothetic cohort of patients with type 2 diabetes. Transition probabilities and utilities were derived from published trials and validated with local clinical experts. Costs were calculated based on resource use from local clinical guidelines and databases from the Ministry of Health and private institutions. The base case was developed based on the demographic characteristics of patients with type 2 diabetes in Colombia with a mean age of 59 years. The analysis was performed from the payer perspective for a time horizon of 20 years. Multivariate sensitivity analysis was performed. **RESULTS:** Our results show that the addition of vildagliptine to metformine yielded an incremental effectiveness of 0.83 QALY's over the 20 years of this cohort when compared to metformine alone. The addition of vildagliptine to metformine + glimepiride combination yielded an minor increase in QALY's of only 0.27. Incremental cost for the addition of vildagliptine to metformine was $COP 3,626,000 ($1,900 USD). The incremental cost of the addition of vildagliptine to the combination of metformine was $COP 9,713,169 ($5,100 USD). The ICER for the addition of vildagliptine to metformine was $COP 4,358,350 ($2,500 USD) and to metformine + glimepiride was $ COP 35,697,647 ($18,700 USD). **CONCLUSIONS:** The addition of vildagliptine to metformine and metformine+glimepiride is a cost-effective alternative for the treatment of diabetes type 2 in Colombia.

**PDB67**

**COMPARATIVE COST-EFFECTIVENESS OF BECAPLERMIN GEL ON WOUND HEALING IN PATIENTS WITH DIABETIC FOOT ULCER: CHANGES IN WOUND SURFACE AREA**

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**OBJECTIVES:** Determine the cost-effectiveness of becaplermin gel for the treatment of diabetic foot ulcers (DFU) relative to good wound care (GWC) alone. **METHODS:** Wound surface area (WSA) reduction rates were used to predict the expected costs and outcomes of wound healing for becaplermin versus GWC cohorts over a 1-year time horizon. Changes in WSA were taken from the Phase 3 pivotal trials. The outcomes of the analysis include the average percent reduction of baseline WSA, the direct costs of DFU therapy and the cost per centimeter squared of WSA reduction. The costs for becaplermin gel and DFU patient evaluation and management were derived from standard cost references. Becaplermin utilization was calculated using the manufacturer's recommended dosing algorithm. The economic perspective was that of the payer. Costs are reported in 2013 US dollars. **RESULTS:** The average WSA at baseline was 2.2 centimeters squared. At 20 weeks in the clinical study the becaplermin group demonstrated a statistically higher probability of complete wound closure compared to the GWC group ($p=0.015$) at 50% versus 35%, respectively. Given the reported WSA reduction rates, becaplermin treated DFU were expected to close 100% at 27 weeks while the GWC group reached an expected 88% reduction in WSA at 52 weeks. When costs were compared by wound closure rates, the cost per 1 centimeter reduction in WSA was $1,285 in the becaplermin group compared to $3,446 in the GWC group. The total expected direct cost of DFU care across the 1-year time horizon was estimated at $6,702 in the GWC group compared to $2,827 in the becaplermin group. **CONCLUSIONS:** DFU patients treated with becaplermin experienced better clinical outcomes than those treated with GWC alone. As a result of the improved outcomes becaplermin demonstrated economic dominance over GWC providing better outcomes at a lower direct cost.

**PDB68**

**COMPARATIVE COST EFFECTIVENESS OF METFORMIN-BASED ORAL HYPOGLYCEMIC THERAPY IN POPULATION-BASED DATABASE**

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**OBJECTIVES:** Although metformin remained the mainstay of oral hypoglycemic agent (OHA), patients receiving combined OHAs significantly increased. We aimed to differentiate real-world effectiveness and economic benefit of metformin-based OHAs, from the perspective of Taiwan's National Health Insurance (NHI). **METHODS:** The NHI Research Database 1999 – 2012 was used, which was derived from the claims of Taiwan NHI, a mandatory-enrollment and single-payment system created in 1995, covering over 99% of the population. Four metformin-based cohorts were extracted: one reference group was metformin plus sulphonylureas (Met-SU), and three comparison groups were metformin plus acarbose (Met-ACA), metformin plus thiazolidinediones (Met-TZD), and metformin plus meglitidine. By using propensity scores, each comparison cohort subject was 1:1 matched to the reference subject on demographics and comorbidity. The effectiveness outcome of interest was diabetes associated cardiovascular disease (CVD) complication risk. Only direct medical costs were included (expressed in 2012 U.S. dollars). A Markov model was applied to project lifetime effectiveness and economic outcomes, discounted at 3% per annum. Bootstrapping technique was used for assessing uncertainty in cost-effectiveness analyses. **RESULTS:** The age-gender weighted average lifetime costs was $94,112.5, of which 61% was attributed to diabetic complications and the managing CVD accounted for 67% of total complication costs. The estimated CVD risk was 34%, with the highest in Met-SU and the lowest in Met-TZD (40% vs. 31%, $p<.05$). After a 10 year follow-up, average expenditure in Met-TZD was highest, due to higher drug acquisition price of TZD. However, over a lifetime, Met-ACA had the highest spending, most attributed to managing diabetic complications. The sensitivity analysis consistently demonstrated the cost-effectiveness of Met-TZD vs. other metformin-based therapies. **CONCLUSIONS:** Over a lifetime, Met-TZD combination was the least expensive and most effective in lowering CVD risk. The results would inform clinical selection of "add-on" therapy in patients with inadequately controlled by metformin.

**PDB69**

**COST-EFFECTIVENESS OF LIRAGLUTIDE FOR SUBJECTS WITH TYPE 2 DIABETES IN SPAIN**

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**OBJECTIVES:** Metformin forms the first-line therapy for patients with type 2 diabetes, but the majority require treatment intensification at some stage due to the progressive nature of the disease. The 1860-LIRA-DPP4 trial showed that, at 52 weeks, liraglutide exhibited greater improvements compared with sitagliptin in HbA1c, blood pressure, serum lipids and BMI in patients with diabetes inadequately controlled on metformin monotherapy. This study compared the long-term clinical and cost implications associated with liraglutide and sitagliptin for subjects with type 2 diabetes in Spain. **METHODS:** Data were taken from the 1860-LIRA-DPP4 trial randomized, controlled trial at 52 weeks, in which adults with type 2 diabetes were randomly allocated to receive either 1.8mg liraglutide or 100mg sitagliptin daily in addition to metformin. Long-term (patient lifetime) projections of clinical outcomes and direct costs (2012 EUR) were made using a published and validated model of type 2 diabetes. Outcomes were discounted at 3% annually. Sensitivity analyses were performed and support the findings. **RESULTS:** Liraglutide was associated with improved clinical outcomes over sitagliptin in terms of life expectancy (14.24 versus 13.87 years) and quality adjusted life-expectancy (9.24 versus 8.84 quality-adjusted life years [QALYs]). Improved clinical outcomes were driven by improved